

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 1999 list were made in February 1999

New Approvals

NADA Number: 140-926

Trade Name: Maxiban®/ BMD®
Ingredients: Narasin/nicarbazin (in a fixed dose combination) and bacitracin methylene disalicylate
Sponsor: Elanco Animal Health, a Division of Eli Lilly & Co.
Approval Date: 01/04/99
Status: Over-the-counter
Route: Oral
Species: Broiler chickens (only)
Drug Form: Type A Medicated Articles to make Type C medicated feeds
Concentration: Narasin/nicarbazin: 36 grams of activity each per pound in the Type A Medicated Article.
Bacitracin methylene disalicylate: 10, 25, 30, 40, 50, 60, or 75 grams of activity per pound of Type A Medicated Article
Indications: For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain and improved feed efficiency.
Tolerance: 21CFR 556.428 Narasin: A tolerance for residues in chickens is not needed. The safe concentrations for total narasin residues in uncooked edible chicken tissues are: 0.6 ppm muscle; 1.8 ppm in liver; 1.2 ppm in skin with adhering fat.
21CFR 556.445 Nicarbazin: A tolerance of 4 ppm is established for residues in uncooked chicken muscle, liver, skin, and kidney.
21 CFR 556.70 Bacitracin: 0.5 ppm negligible residue in uncooked edible tissues of chickens.
Withdrawal: 5 days
Patent No.: 4,218,438 Expiration date: 04/14/1999
4,333,919 09/12/1999
4,405,609 01/22/2001
4,468,380 08/28/2001
4,366,168 09/21/2001
4,665,100 05/12/2004
4,764,534 08/16/2005
4,797,275 01/10/2006

21CFR 558.76, 558.363, and 558.366

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Supplemental Approvals

NADA Number: 095-735

Trade Name : Rumensin® 80
Ingredients: Monensin sodium
Sponsor: Elanco Animal Health, a Division of Eli Lilly & Co.
Approval Date: 12/16/98
Status: Over-the-counter
Route: Oral
Species: Cattle (beef and non-lactating dairy) excluding veal calves
Drug Form: Type A Medicated Article to make Type B and C medicated feeds.
Concentration: 80 g/lb Type A Medicated Article
Indications: For increased rate of weight gain, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* and improved feed efficiency.
Tolerance: A tolerance of 0.05 ppm for negligible residues in the edible tissues has been established. The Acceptable Daily Intake (ADI) is 12.5 ug/kg of body weight/day for total residues.
Withdrawal: Zero days
Patent No.: 4,218,438 Expiration date: 02/14/1999
 4,333,919 09/12/1999
 4,366,168 09/21/2001
 4,405,609 01/22/2001
 4,468,380 08/28/2001
 4,764,534 08/16/2005
Exclusivity: 3 years

This supplemental application provides for a revision of feeding directions, a weight-based dose for prevention and control of coccidiosis, and the establishment of an acceptable daily intake (ADI).

21CFR 556.420 and 558.355

NADA Number: 141-063

Trade Name: Nuflor® Injectable Solution
Ingredients: Florfenicol
Sponsor: Schering-Plough Animal Health Corp.
Approval Date: 12/17/98
Status: Prescription only
Route: Subcutaneous
Species: Cattle
Drug Form: Liquid (solution)
Concentration: 300 mg/mL
Indications: For the control of respiratory disease in cattle at high risk of developing bovine respiratory disease (BRD) associated with *Pasteurella haemolytica*, *Pasteurella multocida*, and *Haemophilus somnus*.
Tolerance: 21CFR 556.283: An acceptable daily intake (ADI) for total residues is 10 micrograms/kilogram of body weight per day. A tolerance of 3.7 ppm for florfenicol amine (the marker residue) has been established in cattle liver (the target tissue). A tolerance of 0.3 ppm for florfenicol amine in cattle muscle is established.
Withdrawal: 38 days
Patent No.: 5,082,863 Expiration Date: 01/21/2009
Exclusivity: 3 years

This supplemental application provides for the addition of a new claim for control of respiratory disease in cattle.

21CFR 522.955

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 141-063

Trade Name: Nuflor[®] Injectable Solution
Ingredients: Florfenicol
Sponsor: Schering-Plough Animal Health Corp.
Approval Date: 01/14/99
Status: Prescription only
Route: Intramuscular or subcutaneous
Species: Cattle
Drug Form: Liquid (solution)
Concentration: 300 mg/mL
Indications: For the treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.
Tolerance: 21CFR 556.283: An acceptable daily intake (ADI) for total residues is 10 micrograms/kilogram of body weight per day. A tolerance of 3.7 ppm for florfenicol amine (the marker residue) has been established in cattle liver (the target tissue). A tolerance of 0.3 ppm for florfenicol amine in cattle muscle is established.
Withdrawal: 28 days if IM or 38 days if SQ
Patent No.: 5,082,863 Expiration Date: 01/21/2009
Exclusivity: 3 years

This supplemental application provides for a new indication for the treatment of interdigital phlegmon within an approved species (cattle).

21CFR 522.955

NADA Number: 116-088

Trade Name: BMD[®]/Coban[®]/3-Nitro[®]
Ingredients: Bacitracin methylene disalicylate, monensin, roxarsone
Sponsor: Alpharma, Inc.
Approval Date: 12/24/98
Status: Over-the-counter
Route: Oral
Species: Broiler chickens
Drug Form: Type A Medicated Article to make Type C medicated feeds
Concentration: BMD[®]: 10, 25, 30, 40, 50, 60, or 75 g/lb in Type A Medicated Article
Coban[®]: 45 or 60 g/lb in Type A Medicated Article
3-Nitro[®]: 45.4, 90, 227, or 360 g/lb in Type A Medicated Article
Indications: For the prevention of coccidiosis in broiler chickens caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*; increased rate of weight gain and improved feed efficiency; and as an aid for the **control** of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin methylene disalicylate.
Tolerance: 21CFR 556.70 Bacitracin: The tolerance is established at 0.05 ppm negligible residue in uncooked edible tissues of chickens, and 0.5 ppm in eggs.
21CFR 556.420 Monensin: The safe concentrations for total residues in edible tissues of chickens are 1.5 ppm in muscle, 3.0 ppm in skin and adhering fat, and 4.5 ppm in liver. A tolerance for a marker residue for monensin in chickens is not needed.
21CFR 556.60 Roxarsone: The tolerances (as residue of arsenic in edible tissues of chickens) are established at 0.5 ppm in uncooked muscle, 2.0 ppm in edible byproducts, and 0.5 ppm in eggs.
Withdrawal: 5 days

This supplemental application provides for the addition of the higher use level of bacitracin methylene disalicylate in broiler chicken feed associated with the claim for control of necrotic enteritis.

21CFR 558.355

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